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PTO/SB/371 (Modified) (Rev. 4-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
23-00061-06	
U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR	
10/070625	
INTERNATIONAL APPLICATION NO. PCT/US00/24791	INTERNATIONAL FILING DATE 08 September 2000
PRIORITY DATE CLAIMED 08 September 1999	

TITLE OF INVENTION

DYNAMIC SPLINT FOR CARPAL TUNNEL SYNDROME TREATMENT

APPLICANT(S) FOR DO/EO/US

George Roger Williams

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include itens (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☒ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☐ Other items or information:

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/070625	PCT/US00/24791	23-00061-06

24. The following fees are submitted:.

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :	CALCULATIONS PTO USE ONLY
☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO $1040.00	
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO $890.00	
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO $740.00	
☒ International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) $710.00	
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) $100.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =	**$710.00**
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	**$0.00**

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	28 - 20 =	8	x $18.00	**$144.00**
Independent claims	4 - 3 =	1	x $84.00	**$84.00**
Multiple Dependent Claims **(check if applicable)**.			☐	**$0.00**
TOTAL OF ABOVE CALCULATIONS =				**$938.00**
☒ Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				**$469.00**
SUBTOTAL =				**$469.00**
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +				**$0.00**
TOTAL NATIONAL FEE =				**$469.00**
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).** ☐				**$0.00**
TOTAL FEES ENCLOSED =				**$469.00**
			Amount to be: refunded	$
			charged	$

a. ☒ A check in the amount of **$469.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☐ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _____ A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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39,706
REGISTRATION NUMBER

March 4, 2002
DATE

DYNAMIC SPLINT FOR CARPAL TUNNEL SYNDROME TREATMENT

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims priority based on inventor's following: U. S. Patent Application Ser. No. 09/391,577, filed on September 8, 1999; U. S. Provisional Patent Application Ser. No. 60/227,225, filed on August 23, 2000.

TECHNICAL FIELD

This invention relates generally to medical therapeutic devices for treating and curing functional disorders of the carpal area of the arm. More particularly, the present invention provides a splint for providing dynamic pressure to the transverse carpal, volar carpal, and intra carpal ligaments, tending to relieve contractures of the ligaments and thus relieving the pain and correcting altered kinematics associated with carpal tunnel syndrome (CTS) by increasing the carpal volume, while providing free movement of the patient's wrist with minimal impediment during activities of daily living. Additionally, the device provides optional adjustable resistance in either direction for

selective, preventative, and therapeutic impetus in reestablishing normal cocontraction for a more permanent, lasting solution.

BACKGROUND ART

A. General Description of the Condition

Carpal tunnel syndrome (CTS) is a painful condition caused by compression of the median nerve of the forearm as it passes through the wrist canal, or carpal tunnel. The median nerve and the flexor tendons pass from the forearm to the hand through the carpal tunnel; compression can result from either a reduction in carpal tunnel volume, swelling of tissues passing through the canal, or both. Prolonged exertion at a keyboard or manual labor are common, but by no means the only, associations of the syndrome. More specifically, CTS is believed to be caused by a biomechanical ligament imbalance in the volar carpal ligaments, namely, a thickening of the palmer transverse carpal ligament (PTCL, also known as the retinacular ligament), a thickening of the volar intracarpal ligaments, and contraction of an assortment of volar carpal ligaments.

Note that throughout this specification, the term "volar" shall be interpreted as "in the direction of the

palm of the hand" and "dorsal" shall be interpreted as the opposite of "volar", that is, in a direction away from the palm of the hand or directed outwardly from the back of the hand. Unless specifically stated otherwise, all descriptions and observations shall be made from the standpoint of an individual's right hand and forearm for consistency and ease of description. The discussion which follows applies equally well to either hand or forearm.

B. Kinematics of the Carpal/Forearm Complex

The flexor muscle tendons of the forearm acting on the wrist, fingers and thumb exert a collective static force power many times greater, volarly, than the extensor muscle tendons acting to stabilize the same members of the wrist and hand dorsally. This interaction between the flexor muscles (antagonist) and the extensor muscles (agonist) which tends to hold the joint in a fixed and stable position is termed "cocontraction." The ratio of these opposing forces is normally four to one flexor to extensor. However, work demands often increase this ratio through hypertrophy of the flexor muscle tendon units by intensity and duration of tasks requiring dominantly finger, thumb, and wrist function.

The effect of the volar flexor forces, acting upon the PTCL as a pulley, attenuate the PTCL and apply forces

anteriorly and medially. This places traction forces to the ligament ends of the carpus. Each night, while the muscles are at rest, the volar intracarpal segments restore their normal position grossly; however, some minute anteriomedial deformity remains, and slack of the PTCL is concurrently taken up by contractile forces of this and the other ligament(s). Numerous cycles of force followed by rest develop an established deforming characteristic which is manifested by narrowing the horseshoe ends of the carpal tunnel, which are held in position by a thickening PTCL and other volar carpal ligaments, resulting in a transverse deformity. Simultaneously, the PTCL acting as a pulley concentrates the load of the finger and thumb function so that a volar glide is initiated, where volar glide is defined as movement of the carpal metacarpal complex as a unit in a volar direction. This volar glide of the carpal metacarpal complex attenuates the predisposed thin dorsal carpal ligaments (DCL) originating from the distal radial ulna (DRU). Since the volar carpal ligaments collectively become less stressed, they begin to contract, thus encouraging the anteriomedial collapse of the intercarpal spaces simultaneous to a longitudinal deformity.

The long moment arm of the carpal muscle tendon units are only capable of stabilization of the carpus

when the muscle tone is within normal limits, i.e. approximately 4 to 1 flexor to extensor, respectively; these forces acting on the carpus in flexion are convergent toward the muscle origin and are regulated by an interplay of antagonists, pulleys and joint alignment. A variation of one or more serves to simplify convergence towards a direct line to this point of origin and shorten the distance therebetween. This force results in a decreasing biomechanical advantage which is manifested by a volar shift of the axis of the proximal carpal row. This may account for the propensity of patients with CTS to develop odd compensatory behaviors like flexing the wrist during power grasping, conceivably to account for the change in position of the more volarly placed PTCL. Carpal tunnel volume is further reduced and any other predisposition will hasten onset of the painful and crippling CTS condition.

Thus, the resistance of the PTCL and related volar ligaments are encountered when returning the carpal metacarpal complex to a neutral position, i.e. dorsal glide, should be indicative of the severity of the condition of carpal tunnel syndrome or the propensity of the subject to incur the condition.

C. Standard Treatment of Carpal Tunnel Syndrome

To date, CTS has been treated with wrist rests, anti-inflammatory medications, cortisone injections, surgery, or static wrist splints. Alone or combined, these treatments have met with varying degrees of minimal success. Symptom relief is short lived and compounded by surgical complications. Even after these treatments are applied, the patient's biomechanical configuration remains unchanged or complicated. Reduced grasp strength has been well documented. The obvious solution, i.e. removing the cause of the injury by refraining from the manual labor believed to cause the problem, is not always practical since the cause of the injury is frequently the means by which the patient obtains his or her livelihood. The next best choice, prevention through proper intervention, can be achieved by enlarging the carpal canal to maintain adequate space for the median nerve and thus avoid compression. However, the mechanism for correcting this condition long term does not exist.

The carpal canal can be enlarged by osteopathic manipulation and stretching maneuvers, thereby alleviating compression on the median nerve and resolving CTS. While severe cases may require other treatment, manipulation is effective in the majority of cases and

has the advantage of being prophylactic, i.e. a preventative. Optimum resolution of the symptoms requires frequent stretching and the assistance of another person, a physician or therapist to perform the manipulation. There is a need for an appliance which a patient can use to augment treatment by the physician or therapist. It is known from studies of rehabilitated knee joints and elbow joints that the longest period of low force stretching produces the greatest amount of permanent elongation of connective tissue. Ideally, the stretching would be accomplished by means of an appliance which is adjusted by the physician or therapist to provide the appropriate force for stretching, preferably continuously.

However, there are a number of difficulties in the use of such appliances. First, simply prescribing the use of an appliance does not mean that the patient will use it properly. If a patient is expected to put on and remove an appliance, a properly adjusted appliance must not be able to be put on incorrectly or to inflict either too much or too little stretching. Proper use also refers to the compliance or self-discipline of the patient and how easy it is to use the appliance. In general, an appliance that is mechanically simple, easy to use, and comfortable to wear will more likely be used as directed.

Second, the skin is sensitive to long term pressure, which can cause a localized loss of circulation and lead to ulceration. Obviously, a patient will not be comfortable if an appliance causes such irritation. On the other hand, sufficient pressure must be applied in order to be effective. Such an appliance must be comfortable to wear and not cause undue irritation or pressure on the skin.

Third, an appliance must not interfere with the normal activities of living. It must be comfortable in the sense that it does not interfere with the function of the arm, wrist, and hand. Otherwise, a patient is unlikely to wear the appliance long enough to be fully effective, preferably overnight, or when performing routine tasks which may irritate the median nerve or promote the deformities. An appliance duplicating the manipulation by a physician or therapist would obviously interfere with the patient's use of the hand. What is desired is an appliance which duplicates as much of the physician's treatment as possible without interfering with the use of the arm, wrist, or hand.

The prior art is replete with splint appliances which are designed to reduce CTS pain. One such appliance is described in U. S. Patent No. 5,417,645, entitled "Flexible Wrist Splint for Carpal Tunnel Syndrome Treatment", which issued to Lemmen on May 23,

1995. The '645 patent provides a splint with an elongated, flexible member having a palmar portion configured to extend from the middle of the forearm, across the volar carpal area, and across the palm to bias the palm in a dorsal direction. It also functions as a reminder of the proper positioning to relieve pressure on the median nerve associated with CTS. It is designed to allow use of the fingers and thumb and to permit near normal hand function.

Another such appliance is described in a series of patents by Davini, i.e. U. S. Patent Nos. 4,966,137 (issued Oct 30, 1990) and its reissue Re. 34,627 (issued May 31, 1994), and 5,385,527 (issued Jan 31, 1995), each entitled "Splint System". Each of these appliances is based upon essentially the same premise, namely, each functions to enlarge the carpal tunnel by compressing the radius and ulna together using an external clamp and bandage configuration which encircles the carpus, so that free use of the hand and fingers is permitted. Stretching of the PTCL or other carpal ligaments is not addressed by these devices.

Still another such appliance is described in U. S. Patent No. 5,468,220, entitled "Carpal Tunnel Bracelet", which issued to Sucher on November 21, 1995. Like the '137 and '627 patents, it also relieves pressure on the median nerve by increasing the volume of the carpal

tunnel. The appliance encircles the carpus and, using spring loaded pads, provides dorsal and volar pressure on the radius, ulna, and other carpal bones which tends to increase tunnel volume. It can be removed by the user if long term use causes irritation or sensitivity to the skin.

Fourth, it is desirable to have an appliance which will not only promote the stretching of the carpal ligaments so as to relieve pressure on the nerve, but also to restore the proper ratio of cocontraction between the flexor and extensor muscles which tend to hold the carpal joint in the proper alignment while carpal ligament stretching is being effected. This encouragement of cocontraction is missing from all existing devices. In order to achieve proper joint stabilization, the device must allow the ligaments to re-engage and reestablish joint stability as well as increasing muscle tone of the flexor and extensor muscles around the perimeter of the joint.

Thus, what is needed is a splint appliance with the following characteristics:

1. The appliance must duplicate the stretching maneuver performed by a trained therapist to stretch the PTCL and collective volar carpal ligaments over time;

2. The appliance must be easily worn and removed by a patient with minimal or no training required for its use;

3. The appliance must not present pressure points to the patient or unduly irritate the skin;

4. The appliance must be easily worn during routine daily life with little or no interference with motion during supination and pronation or during manipulation of the fingers;

5. The appliance must both promote restoration of the carpal ligaments to their proper configuration as well as restore the proper cocontraction of the stabilizing flexor and extensor muscle groups against the carpal joint; and,

6. The appliance must be able to accommodate individuals having different forearm and wrist measurements.

DISCLOSURE OF THE INVENTION

It is therefore an object of the present invention to provide a splint appliance for treating or preventing carpal tunnel syndrome.

Another object of the invention is to provide a splint appliance which is comfortable and can be worn during the normal activities of daily living without unduly interfering with hand movement.

It is a further object of the invention to provide a means to relieve pressure on the median nerve by applying low intensity, extended volar pressure to the hand and thus stretch the palmer transverse carpal ligament.

It is a further object of the invention to promote restoration of the cocontractive forces of the flexor and extensor muscles on the carpal joint to allow the carpal ligaments to be properly stretched and/or contracted so as to achieve a normal configuration.

It is a further object of the invention to provide a splint appliance which can be worn and removed by an unskilled patient without misadjustment.

It is a further object of the invention to provide a splint appliance which will not bind while performing supination or pronation movements but will continue to provide restorative force to the carpus during such movements.

It is a further object of the invention to provide a splint appliance which is simple in construction.

It is a further object of the invention to provide a splint appliance which can be easily adjusted to provide variable tension against dorsal movement of the hand.

It is a further object of the invention to provide a splint appliance which accurately models the kinematics of the carpal/metacarpal complex in order to permit dorsal force to be effectively applied against volar movement.

The invention described herein to satisfy these objects consists of a dynamic orthotic appliance designed to provide low level pressure on the PTCL over extended periods of time while at the same time allowing the user to execute the standard activities of daily living, as well as general activities particular to the user's occupation, without interference from the orthotic. It consists of three components – a biasing component, a forearm component, and a palmar component. The biasing component models the movement of the carpal/metacarpal and distal forearm/carpal joints by employing a unique and innovative tensioning arrangement. It provides continuous, low pressure force which opposes movement of the wrist in a volar direction. The forearm component provides a platform for a biasing component and maintains the biasing component in particular relationship and alignment with the ulnar aspect of the forearm and carpus during all normal movements. The palmar component is positioned on the ulnar side of the hand and is designed to allow unobstructed flexion of the fingers and opposition of the thumb with the fingers; it also couples

the biasing component to the hand. The three components are articulated in a novel manner which allows supination and pronation of the forearm without binding of the appliance or obstructing free movement. It is believed that the placement of the biasing force on the ulnar side of the forearm and hand to avoid interference with daily activities of living and the provisions made to allow the biasing component to track the hand during complex maneuvers of the forearm and hand are novel and new to the prior art.

Further objects and advantages of this invention will become more readily apparent upon reference to the following detailed description of a preferred embodiment, as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a elevation view of the ulnar aspect of an embodiment of the dynamic splint as it relates to the right arm in accordance with the present invention with its major topological features, with the hand shown in a position where the spring is not applying tension against the hand.

FIG. 2 shows the same elevation view of the dynamic splint as in FIG. 1, but with the spring applying dorsal tension against a volar movement of the hand.

FIG. 3 shows a plan view of the forearm component of the one embodiment of the dynamic splint illustrated in FIG. 1. with its major topological features.

FIG. 4 shows an elevation view of the radial aspect of the dynamic splint as it relates to the right arm in accordance with the present invention.

FIG. 5 shows a sectional view of the splint and forearm, illustrating the stabilizing mechanism used for positioning the spring along the ulnar side of the forearm.

FIG. 6 shows a dorsal view of the hand with the palmar component attached the ulnar side of the hand and the positioning of the springs with relationship to the carpus.

FIG. 7 shows the volar view of the hand with the palmar component attached to the ulnar side of the hand.

FIGS 8, 9, and 10 show three views of the connection block used for attaching the spring to the palmar component of the dynamic splint.

FIG. 11 shows the method of securing the end of the spring to the palmar component of the dynamic splint using the connection block.

FIG. 12 shows a plan view of the radial side of the forearm component of the preferred embodiment of the dynamic splint with its major topological features.

FIG. 13 shows a plan view of the ulnar side of the forearm component of the preferred embodiment of the dynamic splint with its major topological features.

FIG. 14 shows a plan view of the forearm component of the preferred embodiment of the dynamic splint illustrated in FIGS. 12 and 13 with its major topological features.

FIG. 15 shows a sectional view of the splint and forearm taken from FIG. 12, illustrating how the dorsal block is employed in the preferred embodiment.

It is to be understood that the present invention is not limited in its application to the details of construction and arrangement of parts illustrated in the accompanying drawings, since the invention is capable of other embodiments, and of being practiced or carried out in various ways within the scope of the claims. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and not of limitation.

BEST MODES OF CARRYING OUT THE INVENTION

A. Definitions

While several terms have been previously defined herein within the context of the discussion, the

terminology to be used in the subsequent detailed description will now be set forth as an aid for those who may not be familiar with these terms as used by the inventor. The terms "volar" and "dorsal" indicate directions of movement or location, where a volar movement is in the direction of the palm of the hand and dorsal movement is in the direction of the back of the hand. Similarly the terms can indicate position, where, for example, a volar carpal ligament would be a ligament located in the carpal complex on the palmar side of the hand. The terms "proximal" and "distal" relate to the position of the described object with relationship to the trunk of the body. Thus, the radius and ulna each has a proximal end (the elbow area) and a distal end (the wrist end). Similarly the carpus is composed of a proximal carpal row of five bones and a distal carpal row of five bones, where the proximal carpal row adjoins the distal end of the radius and ulna. "Supination" is defined as a rotational movement of the radius and ulna which results in a palm up position of the hand, whereas "pronation" is defined as a similar rotational movement resulting in a palm down position of the hand. "Dorsiflexion' is defined as a movement of the hand which forms an arc by extending the wrist dorsally. "Cocontraction" is defined as the interaction between the flexor muscle tendons of the volar forearm acting on the wrist, fingers and thumb,

with the dorsal extensor muscle tendons of the forearm, to stabilize the same members of the wrist and hand, thus tending to hold the carpal joint in a fixed and stable position.

"Glide" is a term used to describe an involuntary movement of the carpal metacarpal complex, whereby the proximal carpal row is said to glide in a shear manner which maintains a parallel relationship with the distal forearm. A volar glide is observed when, with the fingers extended, the palmar plane has moved in a volar direction with relationship to the distal forearm carpal joint, such movement consisting of a shear movement in a volar direction of the proximal carpal row. The magnitude of volar glide is indicative of the severity of CTS. Similarly, a dorsal glide is observed when the dorsal plane of the hand is moved dorsally through a shear movement of the distal forearm carpal joint, an opposite movement of volar glide. "Ulnar deviation" is defined as a movement of the hand in an ulnar direction without either dorsal or volar movement; the plane of ulnar movement is perpendicular to that of dorsal-volar movement. "Radial deviation" is defined as a movement of the hand in a radial direction opposite to that of ulnar deviation.

It has been observed in practice that there is a change is distance between the metacarpals and the distal

ulna-radius during flexion and extension of the hand. This change of distance results in an elliptical path being followed by the hand during its range of motion from flexion to extension. Furthermore, a differential motion has been observed during supination and pronation between the distal and proximal areas of the forearm. It is desirable in any dynamic splint design to mirror these kinematics so that a proper dorsal force can be applied by the splint appliance to resist volar glide.

B. Initial Embodiment

FIG. 1 illustrates an embodiment for a dynamic splint appliance for use in the treatment and prevention of CTS in accordance with the present invention, generally designated by the numeral **10**. The splint appliance **10** consists of a forearm component **20**, a palmar component **30**, and a biasing component **40** and is shown configured in FIG. 1 to the right forearm **50** and right hand **60** of a user with carpal tunnel syndrome. While subsequent descriptions will for consistency and clarity be directed towards use of the appliance **10** with the right forearm of a user, the same appliance can be used on the left forearm and hand of a user, with all elements of the appliance being mirror images of those elements for the right forearm and hand.

The forearm component **20** is shown more generally in the plans of FIGS. 1, 2, and 4. The forearm component **20** is configured as a generally semicircular splint body **100** shown contoured around the dorsal side of the forearm **50** in FIG. 1 and in a flattened plan in FIG. 3. The splint body **100** is oriented on the forearm **50** with its distal edge **120** generally covering the distal radius and ulna, its proximal edge **130** in the direction of the elbow, and its ulnar edge **110** oriented so that it is generally parallel to the ulna (not shown) of forearm **50**. The proximal strap support **140** and the transverse strap fulcrum **160** are wrapped over the dorsum of the forearm **50** so that both extend to points generally adjacent to the radius bone of the forearm **50**, so as to capture only the dorsum of the forearm **50**.

Supination and pronation of the forearm ordinarily cause the biasing component to bind and the forearm component to buckle at the dorsum of the forearm. Cutout **150** on the dorsum of splint body **100** is provided to solve the binding problem. It is generally centered on the dorsum of the forearm **50** and functions to prevent binding of the appliance during supination and pronation. Allowing the distal and proximal ends of splint **100** to move relatively independently of each other while being connected only along the ulnar edge **110** provides a two

point stabilization of the ulnar edge 110 during supination and pronation and maintains alignment of the ulnar edge 110 along the ulnar side of the forearm. The proximal edge 130 of splint body 100 is convexly contoured on forearm 50 along the dorsum towards the distal radial end and away from the proximal radial end so that the extensor muscle group of the forearm is left uncovered and ergonomically accommodated without binding.

Splint body 100 consists of a thin metal core material cut to the shape seen in FIG. 3 and enclosed by a covering material composed of a neoprene external nylon or other anti-perspiration material, such material as is in common use and knowledge among physical therapists, so that the splint body 100 can be molded and customized to individual forearms and trimmed to accommodate individual differences in forearm length and circumference. The exterior of the covering material should is sensitive to attachment by the hook component of an industry standard hook-and-loop system of the type sold under the trademark "VELCRO", so that transverse strap 190 can be removably attached to appropriate areas of the splint body 100, as described below.

Splint body 100 is secured to the forearm 50 by distal forearm strap 170, proximal forearm strap 180, and transverse strap 190. Distal forearm strap 170 is secured

to the splint body **100** by one or more rivets **172**, of which a single representation is shown. The rivet **172** as shown also serves to prevent the biasing component **40** from significant movement either distally or proximally along the ulnar side of the forearm. Distal forearm strap **170** is of sufficient length to allow end **174** having an attached hook and loop fastener strip **177** to be brought around the ulnar side of the forearm, across the distal end of the volar forearm, and over the radial forearm, where end **174** passes through distal buckle **175** and back onto distal forearm strap **170**, where a cooperating hook and loop fastener strip (not shown) is fixed so that end **174** is removably secured to distal forearm strap **170**.

Proximal forearm strap **180** is secured to the proximal strap support **140** by one or more rivets **182**. Proximal forearm strap **180** is of sufficient length to allow end **184** having an attached hook and loop fastener strip **185** to be passed around the radial side of the forearm, across the proximal end of the volar forearm, and over the ulnar forearm, where end **184** passes through proximal buckle **188** and back onto proximal forearm strap **180**, where a cooperating hook and loop fastener strip (not shown) is fixed so that end **184** is removably secured to proximal forearm strap **180**. As shown in this embodiment, proximal buckle **188** is fixedly attached to

the fixed end **186** of transverse strap **190** which is fastened to the splint body **100** by rivet **189**. However, two separate straps could be employed and fastened with separate rivets as required.

Transverse strap **190** is secured to the splint body **100** by rivet **189**. As seen from FIGS 1 and 4, transverse strap **190** follows a line from the proximal ulnar edge of the splint body, across the volar forearm, and over the transverse strap fulcrum **160**, where end **192** having a hook and loop fastener strip **193** is removably secured to the distal strap **170** at an arbitrary point, either by using a cooperating hook and loop fastening strip (not shown) or preferably by attachment directly to the material comprising the distal strap **170** which is sensitive to attachment by the hook component of a standard hook-and-loop fastening means. Transverse strap **190** moves to a limited extent across the transverse strap fulcrum **160**, a portion of splint body **100** which provides a platform for transverse strap **190** against the forearm and prevents it from rubbing or binding during supination and pronation. Because of a differential rotation between the distal end and the proximal ends of the forearm during supination/pronation, the transverse strap **190** tends to stabilize the splint body **100** by translating this differential rotation motion to the ulnar edge **110**, thus

maintaining alignment of the ulnar edge **110** with the ulna.

Referring to FIGS 1, 3, and 5, the biasing component **40** is constructed of a formed wire **200** having a supporting end **202** and a torquing end **204**. The formed wire **200** is preferably made from a length of 24 gauge 304 stainless steel with a B2 finish, as is commonly known to physical therapists in the construction of orthopedic appliances. A plurality of spring loops **206** are formed near the torquing end **204** with each comprised of one or more turns of wire as needed to produce a suitable tensioning force at the torquing end **204** of approximately 8 pounds. Formed wire **202** is enclosed in the covering material **208** along the ulnar edge **110** of splint body **100**, wherein the proximal end of supporting end **202** is allowed to rotate freely within the sheath formed by the covering material as the forearm moves in supination and pronation. Optionally, rivets (not shown) may be placed at the proximal end of the splint body **100** at the ulnar edge **110**, wherein the proximal end of the supporting end **202** is captured between the ulnar edge **110** and the rivet and prevented from migrating within the covering material away from the ulnar edge **110**. An ulnar saddle **210** is formed in the formed wire **200** and positioned over the distal ulna **52** to rotationally stabilize the formed wire

200 during pronation and supination of the forearm. Rivet 172, around which the ulnar saddle 210 is positioned, serves to stabilize the formed wire 200 from significant proximal or distal movement. As seen more particularly in FIG. 5, the ulnar saddle 210 curves from the ulnar side of the forearm 50 up to a point on the dorsum of the forearm and then back to the plane of the ulnar edge 110 of splint body 100.

The spring loops 206 are formed and positioned along formed wire 200 so that they are located laterally on the ulnar side of the ulnar-radial/metacarpal joint and the intra-metacarpal joint and are not covered by distal strap 170. It is believed that each spring loop 206 models the action of the corresponding joint. This double loop spring arrangement has been found to provide sufficient proximal-distal tolerance to accommodate changing distance between the metacarpals and the distal ulna-radius during flexion and extension of the hand, and it thus prevents binding of the palmar component 30 when connected to the torquing end 204. The torquing end 204 of formed wire 200 is shaped so that, when connected with the palmar component 30 and attached to a hand, the hand at substantially 20° of dorsiflexion does not encounter resistance from the biasing component 40.

Although the general loop configuration is the preferred embodiment, other tensioning shapes may be used to provide resistance to movement of the torquing end of the biasing component and still remain within the spirit of the invention, namely, to apply a low force load opposing volar glide over long intervals of time. For example, during testing of the device, an arrangement was formulated (not shown) consisting of slotted bars comprising the support end and torquing end of the biasing component, with a coiled spring wound around a spool, similar to that found in clocks, fixedly connected to the support end. The torquing end rotated about the axis of the coiled spring as the end of the coiled spring applied pressure opposing dorsiflexion. It was found that this arrangement did not track the change in distance between the metacarpals and the distal ulna-radius during flexion and extension of the hand, although this could be accommodated by fashioning a pin in the palmar component that would travel along a slot in the bar comprising the torquing end during flexion. However, a rigid bar of such a configuration would interfere with ulnar and radial deviation during the normal activities of daily living.

It should be noted that normally the range of deviation for a hand is approximately 35° in a radial direction and 45° in an ulnar direction, but much less

range is required to achieve the activities of daily living. The biasing component in the form of a shaped wire **200** allows 20° ulnar deviation, but less restriction on radial deviation, thus permitting a more natural movement of the hand.

Referring now to FIGS. 6 and 7, the palmar component **30** is illustrated as having a rigid ulnar gutter **300** enclosing the ulnar side of the hand and serving as a platform for the fixed attachment of connection block **310**. Ulnar gutter **300** is preferably comprised of a plastic material of any suitable composition to enable it to be custom fitted and shaped to the individual hand. Connection block **310** is permanently affixed to ulnar gutter **300** by any suitable means known to the art, including rivets, screws, glue, or capture in a molded channel in ulnar gutter **300**. Palm strap **320** is permanently affixed to the volar end **302** of the ulnar gutter **300** by means of a rivet **322**, although any suitable means known to the art can be employed. The volar end **302** of ulnar gutter **300** and the volar end **324** of palm strap **320** are shaped so that they are substantially confined between the thenar crease **62** and the MCP joint crease **64** of a typical hand **60** so as to permit unimpeded use of the hand during normal activities of daily living. Palm strap **320** narrows as it passes over the thenar web

66 in order to prevent interference with normal activities. This contouring of palm strap **320** allows unobstructed flexion of the fingers and opposition movement of thumb with that of fingers. The dorsal end **326** of palm strap **320** is removably secured to the dorsal end **304** of the ulnar gutter **300** by cooperating hook and loop attachment strips **328** attached to the palm strap **320** and ulnar gutter **300** by any suitable means. An alternate embodiment (not shown) for palm strap **320** would be to employ the buckling arrangement as described for distal forearm strap **170**, while contouring the shape of the strap to accommodate the thenar crease, the MCP joint crease, and the thenar web as described above.

The construction of connection block **310** is given in FIGS 8, 9, 10, and 11. Connection block **310** is formed of a rectangular block of material, preferably of metal composition, having a top side **319** as shown in FIG. 10, a receiving end **317** as shown in FIG. 9, and a clamping end **318** as shown in FIG. 10. Receiving end **317** has a centrally located horizontal bore **311** which is colinear with the longitudinal axis of connection block **310**. An inclined bore **312** in the same axial plane as the horizontal bore **311** is slantingly positioned so that at receiving end **317** inclined bore **312** does not intersect horizontal bore **311**. Incline bore **312** is slantingly

disposed towards the clamping end **318** and horizontal bore **311**. Inclined bore **312** gradually approaches horizontal bore **311** so that it intersects horizontal bore **311** forming notch **313**, which gradually becomes wider as inclined bore **312** fully intersects and terminates before exiting horizontal bore **311** on its opposite side. Vertical bore **314** intersecting two opposing faces of connection block **310** is perpendicular to the axis of both inclined bore **312** and horizontal bore **311** and is located at the widest point of notch **313**. Vertical bore **314** is threaded to receive set screw **315**. A dado is formed between the inclined bore **312** and the top side **319** of connection block **310**. Top side **319** is fixedly joined to ulnar gutter **300** with its receiving end **317** oriented proximally and its clamping end **318** oriented dorsally as described previously.

During appliance use, the torquing end **204** of formed wire **200** is inserted into the horizontal bore **311** on the receiving end **317** and made to protrude from the clamping end **318**. The ulnar gutter **300** is positioned and strapped to the ulnar side of the hand. Set screw **315** is then tightened against formed wire **200** to force formed wire **200** into notch **313** which clamps the connection block **310** to the formed wire **200**, so that connection block **310**, and consequently the ulnar gutter **300** and the entire palmar

component 30, is constrained from rotational movement about formed wire 200 and from longitudinal motion along formed wire 200 by the clamping action of notch 313 on formed wire 200.

This embodiment of the invention has been described to illustrate one way in which the theory of the invention is implemented in a dynamic orthotic. This embodiment, while effective in treating CTS, has not proven to be conducive to mass manufacture, but it has been presented to show how the problems of preventing binding during supination and pronation and of providing a biasing component with the proper characteristics can be solved without departing from the basic concept of the invention.

C. Preferred Embodiment

The preferred embodiment of the invention is shown in FIGS. 12 through 15. This embodiment has been found to be more manufacturable than the previous embodiment and illustrates how the implementation of biasing component and the solution to prevent binding of the biasing component can differ from the first embodiment and still be within the concept of the invention.

Referring to FIGS. 13 and 14 which illustrate in perspective the ulnar and radial aspect of the orthotic

as it is worn on the right forearm **50**, and to FIG 15 which shows the pattern of the forearm component, the preferred embodiment of the invention consists of orthotic **400** which is also composed of a palmar component **410**, a biasing component **420**, and a forearm component **430**. The palmar component **410** is essentially the same as palmar component **30** described previously.

In describing the forearm component **430** of the preferred embodiment as shown in FIG. 14, it is instructive to compare it with the forearm component **20** of the first embodiment as shown in FIG. 3. Both figures are oriented in the same manner to the right forearm. The body **431** of the preferred embodiment consists of two pieces of a substantial external nylon or other anti-perspiration material, such material as is in common use and knowledge among physical therapists, cut to the shape seen in FIG. 14 and enclosing a core pad of neoprene. Also enclosed within the two layers of covering material are several metal portions which shall be described presently. The covering material should be sensitive to attachment by the hook component of an industry standard hook-and-loop system of the type sold under the trademark "VELCRO", so that distal buckle **175** and proximal buckle **188** of the previous embodiment can be eliminated and transverse strap **440** and distal carpal strap **460** can be

removably attached to appropriate areas of splint body **431**, as described below.

The ulnar support plate **470**, radial support plate **480**, and block plate **490** are sandwiched between the two layers of material composing the splint body **431**. Each plate defines a reinforced area on the orthotic to assist strap attachment to body **431** and to position and orient biasing component **420** to the forearm.

Ulnar support plate **470** is positioned on the ulnar portion **432** of body **431** and radial support plate **480** is positioned on the radial portion **433** of body **431** and in opposing relation to ulnar support plate **470**. Both are composed of plastic, dead soft aluminum (a term familiar to persons knowledgeable in the art), or some other suitable material which is relatively rigid. Dorsal gap **434** separates the ulnar and radial portions of body **431**, with the dorsal strap spanning dorsal gap **434**. A first end of dorsal strap **450** is attached to ulnar support plate **470** by means of rivet **500** inserted through washer **501**, the outer fabric covering of body **431**, ulnar support plate **470**, the inner fabric covering of body **431**, another washer (not shown), and secured in place in the manner of rivets. A second end of dorsal strap **450** is attached to radial support plate **480** in the same manner as the first end and secured by rivet **502** and washer **503**. Dorsal

strap 450 is positioned on the dorsum of forearm 50 (FIG. 12). It is composed of the same material as body 431 and may also contain an expandable portion (not shown) if desired to allow dorsal strap 450 to expand and contract during supination and pronation of forearm 50. It serves to couple the ulnar and radial portions of body 431 to each other in a manner to allow independent movement of said portions without binding but maintaining a general orientation of the portions to forearm 50.

The first end of transverse strap 440 is fixedly attached to radial support plate 480 by means of rivet 504 and washer 505 in the same manner as described previously. The second end of transverse strap 440 has a hook portion 441 sewn thereto and on one side so that it can be wrapped about the volar forearm and attached to the surface of the ulnar distal portion of body 431. Transverse strap 440 corresponds to transverse strap 190 of the first embodiment (FIG. 3), but passes from the radial proximal side of the forearm to the distal ulnar side, rather than from the ulnar proximal side of the forearm to the distal radial side as shown in FIG. 3. Like transverse strap 190, transverse strap 440 stabilizes body 431 by translating differential rotation motion observed in supination and pronation to the radial portion 433 to maintain alignment of radial portion 433

with the radius of forearm **50**. In both cases, transverse strap **190**, **440** loads the supporting end of the biasing component **40**, **420**.

Referring again to FIG. 14, block plate **490** is located on the distal edge **435** of splint body **431** and sandwiched between the two layers of material composing the splint body **431**. It may be composed of a rigid material which may be appropriately formed, such as plastic, dead soft aluminum, and the like. Its function is to provide support for distal carpal strap **460** and to provide a platform for the biasing component **420**. Block plate **490** is comprised of the following three portions: curved portion **491**, horizontal portion **492**, and vertical portion **493**. These portions are shown more clearly in the cross-sectional view shown in FIG. 15. Vertical portion **493** forms a ninety degree angle with horizontal portion **492** at bend **497**; curved portion **491** begins its curvature at bend **496** and continues around the carpus for an arbitrary distance. Construction of block plate **490** out of dead soft aluminum permits curved portion **491** to be easily molded to each individual carpus. Horizontal portion **492** is parallel to the plane **55** defined by the centers of the ulna and radius of forearm **50**. It has been found by experimentation and measurement that the ninety degree orientation between portions **493** and **492**

remains invariant over the range of supination and pronation. Along the angled proximal edge **498** of block plate **490** are two tabs **494** and **495** to accommodate the biasing component which shall be presently described. Tabs **494**, **495** are bent back over portion **492** to capture a section of the biasing component **420** therebetween for rotational movement of biasing component **420**. The first end of distal carpal strap **460** is fixedly attached to block plate **490** by means of rivet **506** and washer **507** in the same manner as previously described for the first end of the dorsal strap. The second end of distal carpal strap **460** has a hook portion **461** sewn thereto and on one side so that it can be wrapped about the carpus and attached to the surface of the distal portion of body **431** to hold body **431** in close contact and orientation with the forearm.

The preferred embodiment of the biasing component **420** is illustrated in FIG. 14. It is comprised spring wire and divided into a torquing end **423**, a middle segment **422**, and a support end **421**, with middle segment **422** and support end **421** being sandwiched between the two layers of fabric comprising the splint body **431** and with torquing end **423** exposed. Torquing end **423** extends from the within body **431** to attach to the palmar component **410** in the same manner as described previously. Along its

extent are two spring loops **424** positioned along the wire so that they are located laterally on the ulnar side of the distal forearm/carpal joint and the carpal/metacarpal joint and slightly dorsal to the axis of the carpus. The two spring loops **424** may optionally be enclosed in a pouch (not shown) composed of the same material comprising the splint body **431** in order to prevent chafing of the ulnar side of the hand and to provide a comfortable pad. Middle segment **422** is loosely captured by tabs **494**, **495** on block plate **491** so that torquing end **423** may swing vertically along portion **493** of block plate **491** without binding. Middle segment **422** is positioned to rotationally stabilize and maintain the position of the formed wire comprising the biasing component **420** during pronation and supination of the forearm. Support end **421** extends along the radial side of forearm **50** so that its end is captured between radial support plate **480** and the outer layer of fabric comprising body **431**. Support end **421** may be bent slightly from the plane formed by torquing end **423** and middle segment **422** to better conform to the radial side of the forearm. To additionally stabilize the biasing component **420**, an ulnar arm **425** formed of spring wire is loosely attached to the wire at the apex of the angle formed by the torqueing end **423** and middle segment **422** by means of a simple loop in its end.

The opposite end of ulnar arm **425** is captured between ulnar support plate **470** and the outer layer of fabric comprising body **431**.

The preferred specifications for the biasing component are as follows. The distance between the proximal spring loop **424** and the bend between middle segment **422** and the torqueing end **423** has been found to be 0.65 inches. The obtuse angle between the middle segment **422** and torquing end **423** should be between 125° and 130°, and the angled proximal edge **498** of block plate **490** should therefore mirror this angle. The obtuse angle between the middle segment **422** and support end **421** should be between 125° and 135°.

D. Use of the Orthotic

The invention is designed to realistically mirror the movement of the hand without interfering with the normal activities of daily living. The biasing component is positioned by the palmar component and the forearm component to reside laterally on the ulnar side of the distal forearm/carpal joint and the carpal/metacarpal joint, and slightly dorsal to the axis of the carpus. This positioning allows the appliance to correctly track the elliptical path that the hand follows during extension and flexion. It is adjusted by the therapist

or at the factory so that force applied by the biasing component is neutral when the palm is at approximately 20° dorsiflexion. When the palm is moved in a volar direction, the biasing component tends to force the palm back to the neutral position at 20° dorsiflexion. This force is resisted by the extensor muscles of forearm 50 which further tends to strengthen the extensors and restore a normal four to one flexor to extensor ratio, which tends to stabilize the carpal-metacarpal joint. At the same time the dorsal attitude of the palm tends to apply a long-term low force against the PTCL and over time will lengthen the ligament and relieve the symptoms of carpal tunnel syndrome.

In the preferred embodiment, the support end of the biasing component sets the tension of the dual springs at the carpus by tightening or loosening the transverse strap, which loads the springs to the desired tension. This permits the tension on the biasing component to be easily adjusted. Furthermore, the design of the biasing component in the preferred embodiment enables the orthotic to fit more individuals because it will accommodate varying sizes of forearm and wrist. Measurable improvement in the patient's condition should be observed in about three to four weeks of continuous use.

While only two embodiments have been illustrated and described, they serve to illustrate obvious modifications which are contemplated within the scope of this invention and the following claims. Accordingly, the scope of the invention should be determined not by the embodiments illustrated but by the appended claims and their legal equivalents.

What is claimed is:

1. An orthopedic appliance adapted to be worn on a forearm and a hand of a person exhibiting symptoms of carpal tunnel syndrome, the appliance comprising:

a. a biasing means alignable with the ulnar side of the forearm and not with the dorsum of the forearm, the biasing means having a supporting end and a torquing end, the torquing end disposed to apply a continuous, low level force to the hand over time and in a direction encouraging dorsal glide;

b. a palmar component coupling the torquing end to the carpal-metacarpal complex of the hand, the palmar component comprising:

i. an ulnar gutter clasp having a dorsal end and a palmar end, the ulnar gutter clasp being sized and configured to the hand such that the dorsal end extends from the ulnar side of the hand to approximately the midpoint of the dorsal side of the hand and the palmar end extends from the ulnar side of the hand to approximately the midpoint of the palm;

ii. a palmar strap having a fixed end and a attachable end, the fixed end permanently secured to the palmar end of the ulnar gutter clasp, the attachable end passing from the

palmar end across the thenar web between the thumb and forefinger to the dorsal end and being removably secured to the dorsal end so as to secure the ulnar gutter clasp firmly to the ulnar side of the hand, and

iii. a connection means fixedly attached to the ulnar gutter clasp at a point proximal to the ulnar side of the hand, whereby the torquing end of the biasing means is coupled to the palmar component at a point outboard of the ulnar side of the hand so as not to interfere with normal activities of daily living; and,

c. a forearm component sized and configured to be rigidly and removably attached to the forearm, the forearm component providing a stable platform for the supporting end and maintaining alignment of the torquing end with the ulnar side of the carpal-metacarpal complex during movement of the forearm and hand;

whereby contractatures of the volar carpal ligaments are relieved and the cocontraction ratio is restored between the flexors and extensors of the forearm, without interfering with normal activities of daily living.

2. The orthopedic appliance described in claim 1, wherein the palmar end is confined within the area of the palm delineated by and interior to the thenar crease of the palm and the MCP joint crease of the palm.

3. The orthopedic appliance described in claim 1, wherein the forearm component comprises the following:

a. a splint shell of semirigid material substantially conforming to the dorsum and sides of the forearm, the splint shell having a distal end, a proximal end, an ulnar edge between the distal end and the proximal end, a radial edge between the distal end and the proximal end, and a dorsal portion extending from the distal end to the proximal end and between the radial edge and the ulnar edge; and

b. a shell securing means for removably securing the splint shell to the forearm.

4. The orthopedic appliance described in claim 3, wherein the proximal end of the splint shell is recessed to permit unimpeded movement of the extensor muscle group on the dorsal side of the forearm.

5. The orthopedic appliance described in claim 3, wherein the shell securing means comprises a distal forearm strap proximate to the distal end and encircling the distal

forearm to removably secure the split shell to the forearm.

6. The orthopedic appliance described in claim 5, wherein the shell securing means further comprises a proximal forearm strap proximate to the proximal end and encircling the proximal forearm to removably secure the split shell to the forearm.

7. The orthopedic appliance described in claim 5, wherein the shell securing means further comprises a transverse strap extending from a point on the splint shell which is proximate to the proximal end and the ulnar edge transversely across the volar forearm to a point on the splint shell which is proximate to the distal end of the radial edge, the transverse strap being releasably secured, whereby the transverse strap maintains alignment of the ulnar edge of the splint shell with the ulna of the forearm during supination and pronation.

8. The orthopedic appliance described in claim 7, wherein the splint shell further comprises a radial gap extending from the radial edge a distance into the dorsal portion, the radial gap defining a proximal portion and a distal portion connected only along the ulnar edge of the splint shell, whereby the proximal portion can move relatively

independently of the distal portion while both the proximal and distal portions maintain alignment of the ulnar edge with the ulna of the forearm during supination and pronation.

9. The orthopedic appliance described in claim 8, further comprising a transverse tab extending proximally from the distal portion a distance generally along the path of the transverse strap and along the radial edge, the transverse tab providing a fulcrum for the transverse strap during supination and pronation of the forearm.

10. The orthopedic appliance described in claim 3, wherein the forearm component further comprises the following:

a. a dorsal gap on the dorsal portion, the dorsal gap extending distally a distance from the proximal end and terminating a distance from the distal end, the dorsal gap defining an ulnar portion and a radial portion, the ulnar and radial portions each extending a distance from the proximal end of the splint shell and unconnected along the distance; and

b. a dorsal strap extending over the dorsum of the forearm and spanning the dorsal gap, the dorsal strap having a first end fixedly connected to the ulnar portion and a second end fixedly connected to the radial portion,

whereby the radial and the ulnar portions move independently within the confines of the dorsal strap.

11. The orthopedic appliance described in claim 10, wherein the forearm component further comprises a reverse transverse strap extending from a point on the splint shell which is proximate to the proximal end and the radial edge transversely across the volar forearm to a point on the splint shell which is proximate to the distal end and the ulnar edge, the reverse transverse strap being releasably secured, whereby the reverse transverse strap maintains alignment of the ulnar edge of the splint shell with the ulna of the forearm during supination and pronation.

12. The orthopedic appliance described in claim 11, wherein the biasing means is a continuous wire from which the supporting end and the torquing end are composed with a middle segment therebetween, the torquing end positioned along the ulnar side of the forearm and hand, the torquing end having at least two adjoining coils fabricated along the length of the torquing end, the adjoining coils positioned laterally to the distal forearm/carpal and the carpal/metacarpal joints and slightly dorsal to the axis of the carpus, the middle segment passing over the dorsum of the forearm, the

supporting end positioned along the radial side of the forearm in attachment with the radial portion, the middle segment serving as an axis of rotation for the supporting end and the torquing end, the reverse transverse strap controlling the dorsal attitude of the torquing end through tension applied to the radial portion and therefore the supporting end.

13. The orthopedic appliance described in claim 12, wherein a first obtuse angle is formed between the middle segment and the supporting end and a second obtuse angle is formed between the middle segment and the torquing end, whereby the torquing end provides both a force resisting volar glide and simultaneously a slight force promoting ulnar deviation as tension is volarly increased against the supporting end by the reverse transverse strap.

14. The orthopedic appliance described in claim 1, wherein the biasing means comprises a spring having an axis associated with the supporting end, the spring being undamped, the supporting end attached to the forearm component and alignable with the ulnar side of the forearm while the axis is distally positioned on the ulnar side of the forearm, the torquing end attached to the ulnar side of the palmar component to provide torque opposing volar movement of the palmar component at

substantially 20° of dorsiflexion or less, the supporting end maintaining orientation of and stabilizing the biasing means along the ulnar aspect of the forearm during supination and pronation.

15. The orthopedic appliance described in claim 14, wherein the axis of the spring is approximately positioned on the ulnar side of the distal forearm/carpal and carpal/metacarpal joints and slightly dorsal to the axis of the carpus, whereby an elliptical arc is formed that maintains placement of the palmar component throughout extension and flexion of the hand.

16. An orthopedic appliance adapted to be worn on a forearm and a hand of a person exhibiting symptoms of carpal tunnel syndrome, the appliance comprising:

a. a palmar component sized for attachment to the carpal-metacarpal complex of the hand;

b. a biasing component alignable with the ulnar side of the forearm, the biasing component formed of a continuous wire with a supporting end and a torquing end, the torquing end coupled to the palmar component and having a plurality of adjoining coils formed along its length; and,

c. a forearm component sized and configured to be rigidly and removably attached to the forearm, the

forearm component providing a stable platform for the supporting end and maintaining alignment of the torquing end with the ulnar side of the carpal-metacarpal complex during movement of the forearm and hand, the coils disposed thereby to apply a dorsally-directed force to the hand.

17. The orthopedic appliance described in claim 16, wherein the plurality of adjoining coils are positioned laterally to the distal forearm/carpal and the carpal/metacarpal joints and slightly dorsal to the axis of the carpus.

18. The orthopedic appliance described in claim 16, wherein the forearm component is comprised of:

a. a splint shell substantially conforming to the dorsum and sides of the forearm, the splint shell having a distal end, a proximal end, an ulnar edge between the distal end and the proximal end, a radial edge between the distal end and the proximal end, and a dorsal portion extending from the distal end to the proximal end and between the radial edge and the ulnar edge; and,

b. a shell securing means for removably securing the splint shell to the forearm.

19. The orthopedic appliance described in claim 18, wherein the splint shell is composed of a semi-rigid material.

20. The orthopedic appliance described in claim 18, wherein the shell securing means comprises a transverse strap extending from a point on the splint shell which is proximate to the proximal end of the ulnar edge transversely across the volar forearm to a point on the splint shell which is proximate to the distal end of the radial edge, the transverse strap being releasably secured, whereby the transverse strap maintains alignment of the ulnar edge of the splint shell with the ulna of the forearm during supination and pronation.

21. The orthopedic appliance described in claim 20, wherein the splint shell further comprises a radial gap extending from the radial edge a distance into the dorsal portion, the radial gap defining a proximal portion and a distal portion connected only along the ulnar edge of the splint shell, whereby the proximal portion can move relatively independently of the distal portion while both the proximal and distal portions maintain alignment of the ulnar edge with the ulna of the forearm during supination and pronation.

22. The orthopedic appliance described in claim 21, further comprising a transverse tab extending proximally from the distal portion a distance generally along the path of the transverse strap and along the radial edge, the transverse tab providing a fulcrum for the transverse strap during supination and pronation of the forearm.

23. The orthopedic appliance described in claim 18, wherein the shell securing means comprises a reverse transverse strap extending from a point on the splint shell which is proximate to the proximal end and the radial edge transversely across the volar forearm to a point on the splint shell which is proximate to the distal end and the ulnar edge, the reverse transverse strap being releasably secured, whereby the reverse transverse strap maintains alignment of the ulnar edge of the splint shell with the ulna of the forearm during supination and pronation.

24. The orthopedic appliance described in claim 23, wherein the forearm component further comprises the following:

a. a dorsal gap on the dorsal portion, the dorsal gap extending distally a distance from the proximal end and terminating a distance from the distal end, the dorsal gap defining an ulnar portion and a radial portion, the ulnar and radial portions each

extending a distance from the proximal end of the splint shell and unconnected along the distance; and

b. a dorsal strap extending over the dorsum of the forearm and spanning the dorsal gap, the dorsal strap having a first end fixedly connected to the ulnar portion and a second end fixedly connected to the radial portion,

whereby the radial and the ulnar portions move independently within the confines of the dorsal strap.

25. The orthopedic appliance described in claim 24, wherein the biasing component further comprises a middle segment connecting the supporting end and the torquing end, the torquing end positioned along the ulnar side of the forearm and hand, the middle segment passing over the dorsum of the forearm, the supporting end positioned along the radial side of the forearm in attachment with the radial portion, the middle segment serving as an axis of rotation for the supporting end and the torquing end, the reverse transverse strap adjustably controlling the dorsal attitude of the torquing end through tension applied to the radial portion and therefore the supporting end.

26. The orthopedic appliance described in claim 25, wherein a first obtuse angle is formed between the middle segment

and the supporting end and a second obtuse angle is formed between the middle segment and the torquing end, whereby the torquing end provides both a force resisting volar glide and simultaneously a slight force promoting ulnar deviation as tension is volarly increased against the supporting end by the reverse transverse strap.

27. An orthopedic appliance adapted to be worn on a forearm and a hand of a person exhibiting symptoms of carpal tunnel syndrome, the appliance comprising:

a. a palmar component sized for attachment to the carpal-metacarpal complex of the hand, the palmar component comprising:

i. an ulnar gutter clasp having a dorsal end and a palmar end, the ulnar gutter clasp being sized and configured to the hand such that the dorsal end extends from the ulnar side of the hand to approximately the midpoint of the dorsal side of the hand and the palmar end extends from the ulnar side of the hand to approximately the midpoint of the palm;

ii. a palmar strap having a fixed end and a attachable end, the fixed end permanently secured to the palmar end of the ulnar gutter clasp, the attachable end passing from the palmar end across the thenar web between the

thumb and forefinger to the dorsal end and being removably secured to the dorsal end so as to secure the ulnar gutter clasp firmly to the ulnar side of the hand, and

iii. a connection means fixedly attached to the ulnar gutter clasp at a point proximal to the ulnar side of the hand;

b. a biasing component alignable with the ulnar side of the forearm, the biasing component formed of a continuous wire with a supporting end and a torquing end, the torquing end coupled to the connection means of the palmar clasp, the torquing end having a plurality of adjoining coils formed along its length; and,

c. a forearm component sized and configured to be rigidly and removably attached to the forearm, the forearm component providing a stable platform for the supporting end and maintaining alignment of the torquing end with the ulnar side of the carpal-metacarpal complex during movement of the forearm and hand, the coils disposed thereby to apply a dorsally-directed force to the hand.

28. A method of relieving the pain associated with carpal tunnel syndrome and increasing the carpal volume through use of an appliance sized and configured to a forearm and

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a hand of an individual person manifesting pain, the appliance having a forearm component, a palmar component, and a biasing component formed of a wire having a supporting end, a torquing end, and a plurality of adjacent coils formed therebetween, the method operating to relieve contractatures of the volar carpal ligaments and to restore the cocontraction ratio between the flexor and extensor muscle tendons of the forearm, without interfering with normal activities of daily living, the method comprising the steps of

a. releasably attaching the forearm component in fixed relation to the dorsal side of the forearm, the forearm component serving to position the supporting end of the biasing component in fixed relationship to the ulnar side of the forearm;

b. releasably attaching the palmar component of the appliance in fixed relationship to the ulnar side of the hand associated with the forearm upon which the forearm component is positioned, so that the palmar component permits free movement of the hand during normal activities of daily living;

c. fixedly connecting the torquing end of the biasing component to the ulnar side of the palmar component;

d. positioning the coils of the biasing component adjacent to the ulnar side of the ulnar-radial/metacarpal and intra-metacarpal joints;

e. Adjusting the biasing component to support the hand at about 20° dorsiflexion where no force is exerted upon the metacarpal complex of the hand by the biasing component;

f. adjusting the biasing component to provide low level resistance against dorsally- or volarly-directed volitional hand movement diverging from the 20° dorsiflexion point;

g. maintaining alignment of the biasing component in the position on the ulnar side of the ulnar-radial/metacarpal and intra-metacarpal joints during supination and pronation of the forearm and during ulnar/radial deviation of the carpal-metacarpal complex; and

h. permitting unobstructed flexion of the fingers and opposition of the thumb with the fingers.

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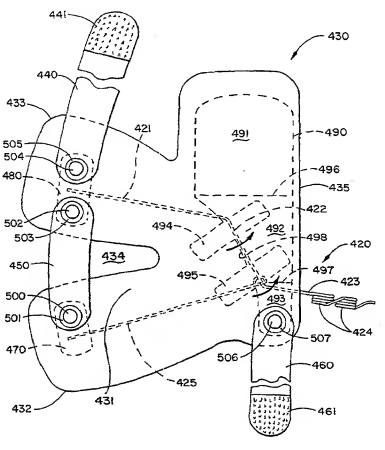
(54) Title: DYNAMIC SPLINT FOR CARPAL TUNNEL SYNDROME TREATMENT



(57) Abstract: A method and apparatus for a splint appliance to apply dynamic pressure to the transverse carpal, volar carpal, an intra carpal ligaments, tending to relieve contractures of the ligaments and thus relieving the pain and correcting altered kinematics associated with carpal tunnel syndrome, thus increasing the carpal volume, while providing free movement of the patient's wrist with minimal impediment during activities of daily living, both at home and at work. The apparatus consists of a forearm component (431) representing the splint body and designed to maintain alignment and support for a biasing means (420) positioned on the ulnar side of the forearm (50), the biasing means (420) consisting of a spring (424) located at approximately the ulnar side of the carpus and connected to a palmar component (410) fastened to the ulnar side of the hand. The biasing component (420) provides resistive force to volar glide in a manner which accurately models the kinematics of the carpus and forearm.

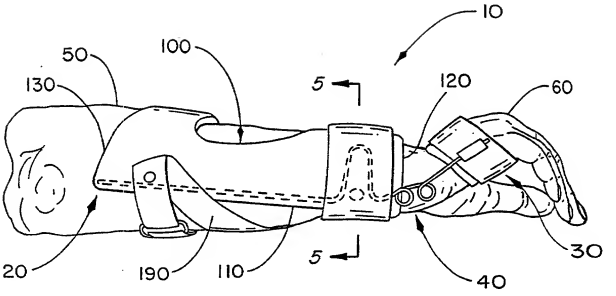


FIG. 1

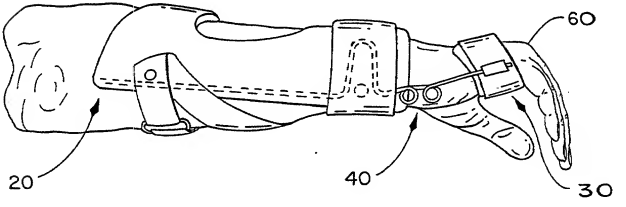


FIG. 2

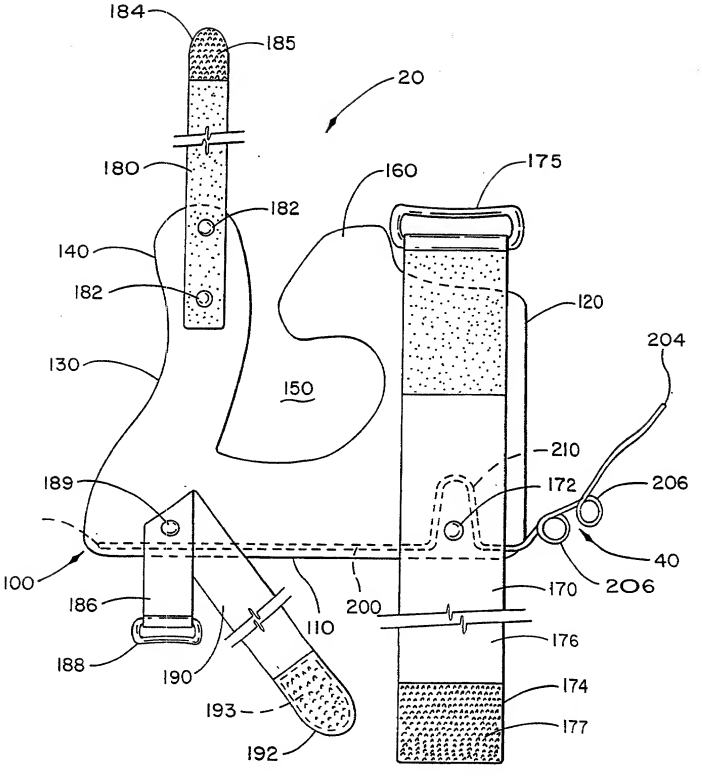

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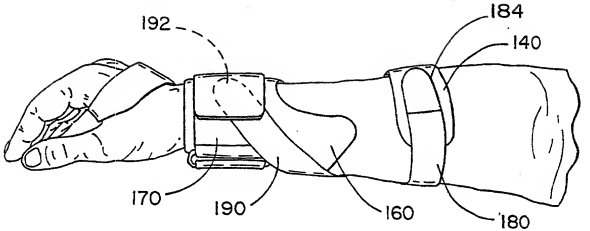
FIG - 3



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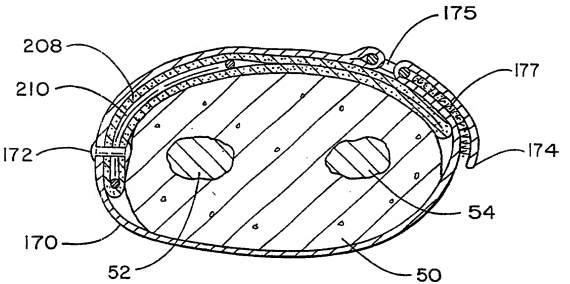


FIG - 5

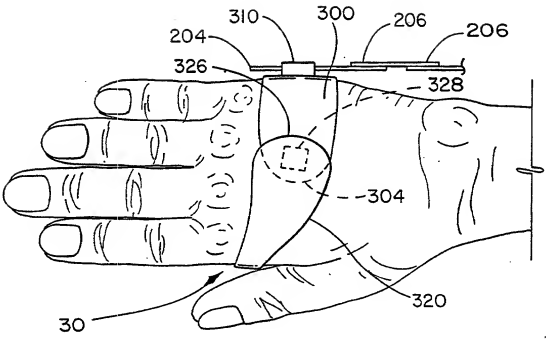


FIG. 5

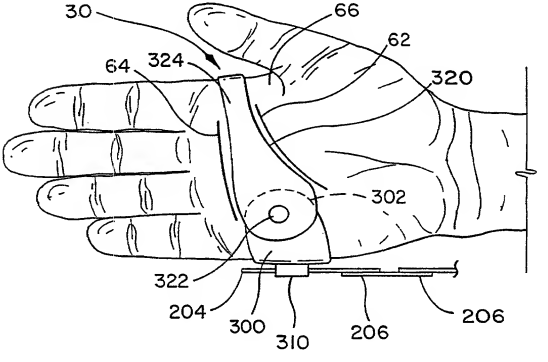
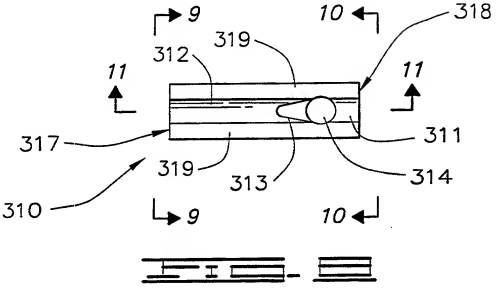
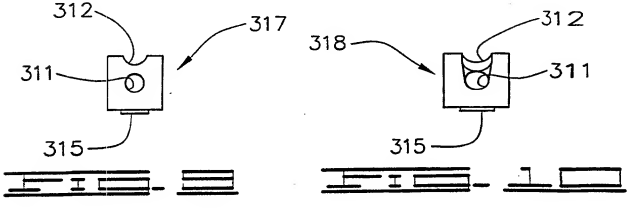
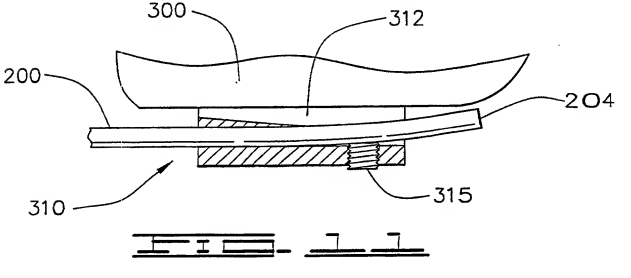


FIG. 7







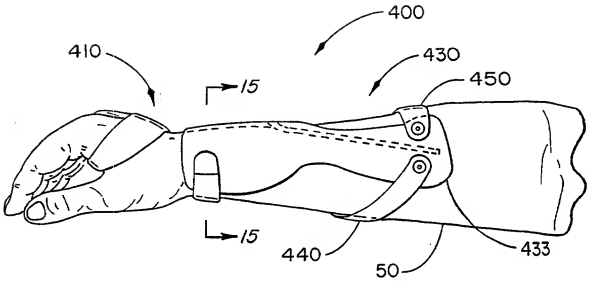


FIG. 12

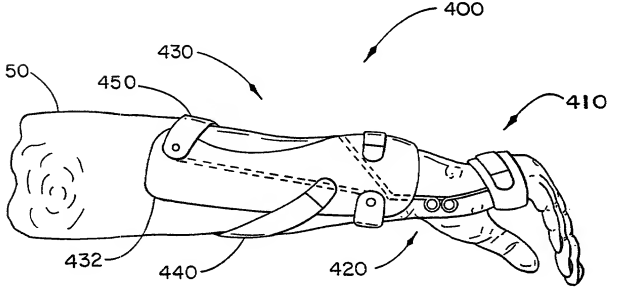


FIG. 13

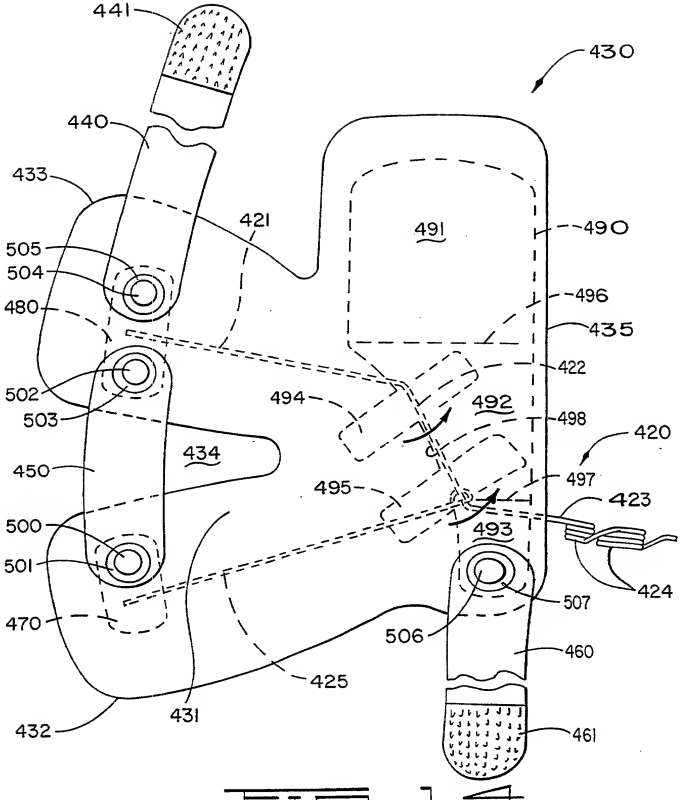

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FIG. 14

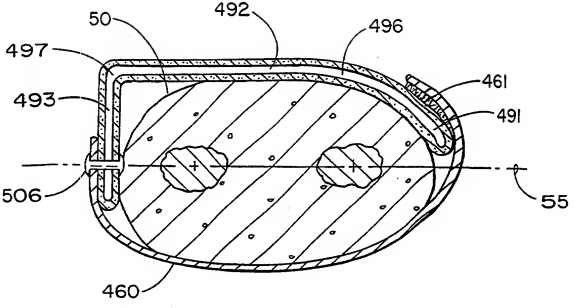

FIG. 15

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted with Initial Filing **OR** ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e))

Attorney Docket Number	**23-00061-06**
First Named Inventor	**George Roger Williams**
COMPLETE IF KNOWN	
Application Number	/
Filing Date	**March 4, 2002**
Group Art Unit	**3764**
Examiner Name	**Pothier, D**

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

DYNAMIC SPLINT FOR CARPAL TUNNEL SYNDROME TREATMENT

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on **September 8, 2000** as United States Application Number or PCT International Application Number **PCT/US00/24791** and was amended on (MM/DD/YYYY) **October 16, 2001** (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above:

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign		Foreign Filing Date	Priority	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
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☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
60/227,225	**08/23/2000**	☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

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Name	James F. Harvey, III	20491 PATENT_TRADEMARK OFFICE	
Address	3750 West Main Street, Suite 130		
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City	Norman	State OK	ZIP 73072-4645
Country	US	Telephone (405) 447-4934	Fax (405) 321-8581

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NAME OF SOLE OR FIRST INVENTOR :		☐ A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any]) George Roger		Family Name or Surname Williams	
Inventor's Signature			Date March 4, 2002
Residence: City Edmond	State OK	Country US	Citizenship US
Mailing Address 3024 SE 40th Street			
Mailing Address			
City Edmond	State OK	ZIP 73013	Country US

NAME OF SECOND INVENTOR:		☐ A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])		Family Name or Surname	
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
Mailing Address			
City	State	ZIP	Country

☐ Additional inventors are being named on ____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.